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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,347	07/05/2005	Robert Eckl	4606-P03677US0	7757

110 7590 11/02/2007  
DANN, DORFMAN, HERRELL & SKILLMAN  
1601 MARKET STREET  
SUITE 2400  
PHILADELPHIA, PA 19103-2307

EXAMINER

LEWIS, PATRICK T

ART UNIT	PAPER NUMBER
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1623

MAIL DATE	DELIVERY MODE
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11/02/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/541,347

Applicant(s)

ECKL ET AL.

Examiner

Patrick T. Lewis

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 9-13 is/are rejected.
- 7) ☒ Claim(s) 7 and 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

**DETAILED ACTION*****Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-4, 6 and 9-10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 13 of U.S. Patent No. 6,242,644. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Compound IA of '644 differs from the instantly claimed compound in that Rb' (G) is hydroxycycloalkoxy which is a genus of glycosyl; however, one a glycosyl moiety would have been easily envisioned by one of ordinary skill in the art. '644 also differs from claim 10 in that it is drawn to a pharmaceutical composition; however, the

Art Unit: 1623

formulation of a pharmaceutically active compound into a composition (i.e., active compound + carrier) is *prima facie* obvious.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 2-5, 9 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the limitation "R<sup>1</sup> is a...group of formula COOR<sup>4</sup> or CONR<sup>5</sup>R<sup>6</sup>" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claim 3 recites the limitation "R<sup>4</sup> is a hydrogen atom...or benzyl radical" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claim 4 recites the limitation "R<sup>1</sup> is a hydrogen...or COOEt" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claim 5 recites the limitation "R<sup>1</sup> is a group...or heterocycloalkyl ring" in lines 2-9. There is insufficient antecedent basis for this limitation in the claim.

Claim 9 recites the limitation "R<sup>2</sup>, each independently...or benzyloxy groups" in lines 2-4. There is insufficient antecedent basis for this limitation in the claim.

Applicant's descriptions of terms on pages 3-9 of the specification have been noted; however, said descriptions do not correspond to art-recognized definitions. For

Art Unit: 1623

example, one of ordinary skill in the art would not consider a "carboxylic acid" to be an "heteroalkyl".

In claim 12 it is unclear whether the invention is drawn to a method for inhibiting blood clotting in a patient in need thereof or to a method for the treatment and/or prevention of a thromboembolic condition.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 1623

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
8. Claims 1-4, 6 and 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ackermann et al. US 6,242,644 (Ackermann).

Claims 1-4, 6 and 9 are drawn to compounds of formula (I). Claim 10 is drawn to a pharmaceutical composition comprising a compound of formula (I). Claims 11-13 are drawn to a method for inhibiting blood clotting in a patient in need thereof comprising administering a pharmaceutical composition comprising a compound of formula (I).

Ackermann teaches compounds of formula (IA) corresponding to instantly claimed compounds of formula (I) (claim 16). The compounds of formula (I) inhibit the formation of coagulation factors Xa, IXa and thrombin induced by factor VIIa and tissue factor (column 18, lines 1-11). These compounds consequently influence both platelet aggregation which is induced by these factors and plasmatic blood coagulation. They therefore inhibit the formation of thrombi and can be used for the control or prevention of diseases, such as thrombosis, apoplexy, cardiac infarction, inflammation and arteriosclerosis. Furthermore, these compounds have an effect on tumor cells and prevent metastases. They can therefore also be employed as antitumor agents.

Compound IA of Ackermann differs from the instantly claimed compound in that Rb' (G) is hydroxycycloalkoxy which is a genus of glycosyl; however, one a glycosyl moiety would have been easily envisioned by one of ordinary skill in the art.

### ***Conclusion***

9. Claims 1-13 are pending. Claims 1-6 and 9-13 are rejected. Claims 7-8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Contacts***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on Monday - Friday 10 am to 3 pm (Maxi Flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1623

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Dr. Patrick T. Lewis  
Primary Examiner  
Art Unit 1623

ptl